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METHOD FOR MANUFACTURING CONTACT OPTICAL OBJECTS
[VERFAHREN ZUR HERSTELLUNG VON KONTAKTOPTISCHEN GEGENSTÄNDEN]

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METHOD FOR MANUFACTURING CONTACT OPTICAL OBJECTS /1*

The present invention relates to an improved method for defect-free mass production of contact optical objects free of tension, e.g. contact lenses or shells, scleral shells, intraocular lenses, etc. according to a pressing method, of transparent thermoplastic material by reshaping of blanks that already have the weight of the final lens or shell between convex and/or convex and concave pressing stamps under pressure at temperatures above the glass transition temperature of the thermoplastic material, but below its melting temperature.

Currently, contact lenses or shells are generally manufactured in one of the following ways:

First, so-called buttons or blanks are manufactured of the desired material. These are blanks that weigh approx. 500 mg, which is a multiple of the weight of the finished lens or shell. During the blank manufacturing of thermoplastic materials, the blanks or buttons /2
are formed from the polymer melt by injection molding. For duroplastic materials, the finished polymer is provided in the form of rods that are sawed or materials that are not yet completely reacted are polymerized or vulcanized directly into small cups with the shape corresponding to the blank. The lenses or shells are manufactured from these blanks by material-removing machining, i.e. by milling, turning, grinding and polishing. The finished contact lens finally weighs about 15 to 30 mg. This method not only takes a lot of work, but also over 10 times the valuable contact lens material. This material is

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*Numbers in the margin indicate pagination in the foreign text.

especially costly with special polymers manufactured for medical use.

Another method for manufacturing contact lenses or shells consists in that a polymerizable reaction mixture or solution that is not yet reacted into molds with concave and convex surfaces and the reaction mixture is allowed to react after the mold is joined together. Actually no material loss occurs with this method, but it is restricted to duroplastic or vulcanizing systems, e.g. on the basis of silicones or methacrylic acid oxyalkyl esters. The state of the art already discussed is described, e.g. in the following documents:
PCT application WO 82/04221, German OLS 2 712 437, 2 838 710, 2 839 /3
249, 2 941 264 and 2 949 951.

According to another method used in practice, polymer powder is pressed to form lenses or shells between dies. The method is actually restricted to thermoplastic materials, but supplies lenses and shells with better surface quality in comparison to the material-removing method. It is especially advantageous for manufacturing lenses or shells with an inner shape that is not spherical. In the method mentioned, the material in powder form is poured into molds and then sintered under pressure at high temperature to form lenses. One disadvantage of this sintering method is that often the powder particles do not sinter or level uniformly, that gas inclusions or vacuoles occur and that the optical purity of the material cannot be examined until after the lens is manufactured. The method is actually less expensive than the material-removing method since the material requirement is also far less, but there are greater chances of flaws

due to impurities. Therefore, the scrap rate during lens manufacturing is generally very high. Besides that there is a danger or impurities during the powder manufacturing due to electrostatic attraction of foreign particles from the environment and/or by humidity and vapors, especially during processing of cellulose esters of aliphatic carboxylic acid or of homopolymers or copolymers of methacrylic acid esters. The contamination with a grain of powder that has a refractive index that differs from the remaining powdered contact lens material /4 only in the 4th digit after the decimal already leads to a recognizable haze in the finished lens or shell.

The object of the invention was to invent a new pressing method that involves fewer sources of flaws and supplies contact optical objects with improved homogeneity, less haze, lower tension and thus higher radial stability.

The object is achieved in that the thermoplastic material is first extruded continuously from the melt to form bands of film, preferably with a thickness of 0.1 to 1.0 mm and especially 0.15 - 0.4 mm. These are smoothed on rollers while being cooled, optically defective locations on the band are marked or eliminated, small blank slabs are cut or punched out and these are reshaped between pressing dies in a mold under pressure at temperatures between at least 20°C and maximum 80°C above the glass transition, but still below the melting temperature, to a stress-free molded element, which after cooling is removed from the mold and/or from the pressing tool.

According to this, the object of the present invention is a

method for manufacturing contact optical objects of transparent materials that can be processed thermoplastically by forming under pressure and heating, which is characterized in that optically /5 flaw-free blanks with the weight of the molded element to be produced are stamped or cut from uniformly thick film and these are reshaped between two dies, according to the geometries of the molded elements to be formed, in a molding tool at temperatures between 20°C and 80°C above the glass transition temperature of the thermoplastic material, pressure with a pressure of 1 to 100 kg/cm^2 and preferably during a period of 5 to 120 minutes.

The manufacturing of the film bands to use according to the invention can be carried out on the usual single-shaft or dual-shaft worm extruders with wide slot nozzles and smoothing rollers or calenders mounted after them. The weight of the punched blank slabs results from their diameter and the film thickness.

For reshaping, e.g. pressing tools of glass, quartz or metals with polished surfaces are used. The pressing tools have geometries corresponding to the desired lenses, shells, etc. The method according to the invention for is especially advantageous for manufacturing lenses with inner surfaces that are not spherical, lenses with specific flattening of the curvature toward the edge, lenses for patients with protrusion of the cornea (keratoconus lenses) and of lenses that will represent a precise counterpart to the entire chamber at the front of the eye, i.e. scleral shells. Such so-called asphericals can only be manufactured with great difficulty using

material-removing methods.

In the method according to the invention, the film slabs are brought between convex and concave stamping dies in molding tools that prevent the escape of the thermoplastic material during the reshaping process. The reshaping to contact lenses, contact shells, etc. occurs under pressure, generally at 1 to 100 kg/cm^2 and preferably at 20 to 100 kg/cm^2. Basically, hither pressures are also possible, but then the danger exists that thermoplastic material will be pressed into the mold edge and the mold will be baked shut; after that it can no longer be opened without destroying the molded element. The reshaping occurs at a temperature of at least 20°C over the glass transition temperature of the thermoplastic material, but at temperatures that are no higher than 80°C, and preferably 60°C, over the glass transition temperature even before the softened material has reached the melting state. A suitable temperature range for thermoplastic materials on the basis of cellulose acetobutyrate, as described for example in DE-OS 2 807 663, lies at e.g. 141°C and 181°C and 120°C to 160°C for copolymers of methyl methacrylate with acrylic acid methylester. Generally, the pressure is at least 1 kg/cm^2, preferably at least 5 kg/cm^2 and should not exceed 100 kg/cm^2. The duration of the reshaping process is generally 5 minutes and preferably up to about 60 minutes. Shaping times longer than 120 minutes have no advantage and usually lead to thermal damage to the material. /6

The pressing tools consist of material that is pore-free, e.g. of glass, quartz, ceramic or metals (chrome-plated steel, precision /7

pressing alloys based on tin, lead, silver, antimony and bismuth). The surfaces are advantageously coated, especially the concave stamping surfaces that stamp the contact lens on the surface turned toward the eye. The surface roughness should lie below 0.02 µm. One pressing tool, among others, that can be considered is described in DOS 2 806 388.

It is very advantageous for the quality of the contact optical molded elements to be produced, if the blank slabs that are placed in the mold before reshaping already have the precise weight of the desired molded element, within approx. ± 0.5 mg. If the slabs are too light they do not fill the molds completely; lenses occur with incompletely formed edge zones. If the blanks are too heavy, the lenses will be too thick, especially in the edge area.

Thermoplastic materials that are especially suitable for processing using the method according to the invention are cellulose ester aliphatic carboxylic acids, especially in the form of low molecular polymer blends free of softener with e.g. polyethylene/vinyl acetate copolymers, high molecular aliphatic polyesters or polyester carbonates and/or also polyacrylic acid methylester/acrylic acid butylester copolymers, as described e.g. in DE-OS 2 807 663, DE-OS 3 314 188 and US-PS 4 263 183. According to the invention, /8 other suitable thermoplastic, optically transparent materials include poly-4-methyl-pentene-1, aromatic polycarbonates, stellate styrene/butadiene block polymers, polyamides with cycloaliphatic diamines and especially homopolymers or copolymers of methacrylic acid

esters like polymethyl methacrylate or methyl methacrylate/methylacrylate copolymers.

The contact optical molded elements manufactured using the method according to the invention are distinguished by special optical purity, few inclusions, air bubbles or vacuoles, by an exact edge structure, low surface roughness of under 0.02 µm, as well as freedom from haze. The lenses or shells are free of tension and have outstanding radial stability even with long storage or wearing time.

Examples /9

A polymer blend of 95 weight-% cellulose acetobutyrate (hydroxyl content: 1.7 weight-%, butyric acid content: 46 weight-%, acetic acid content: 20 weight-%) and 5 weight-% polyethylene co-vinylacetate (with 70 weight-% vinylacetate percentage) with a glass transition temperature of 111°C was extruded through a wide slot nozzle on a conical dual-shaft extruder at 190°C to form a film band 40 mm wide and 0.3 mm thick, which was smoothed and cooled on a three-roller loom. Circular small slabs with 9 mm diameter and 18.3 mg weight were stamped from this film. A concave glass stamp with a radius of curvature of 8.25 mm and an aspherical edge surface was placed in a guide sleeve. After that a blank slab was put in and the mold with a convex glass stamp, with a front surface radius that corresponds to a vertex power of the lens of -2.25 diopters, was closed. The reshaping device was loaded with 10 kg and heated in a recirculating air oven to 160°C within 45 minutes. The tool was allowed to cool, loosened from the guide sleeve and the les was loosened from the glass stamp in ice

water. The edge zone was precisely formed and it was possible to bring it to the required thickness by polishing. The lens was hydrated for 2 days in physiological saline solution.

After that, the change in radius was tested over a period of 30 days. The following changes resulted:

After days	Angling[x)]	Flattening[x)]	/10
1	0.035 mm		
2	0.02 mm		
5	-	-	
30	-	0.01 mm	

[x)] The values relate to the change with respect to the previous value

The example was repeated, by starting with a copolymer of 95 weight-% methacrylic acid methylester and 5 weight-% acrylic acid methylester (intrinsic viscosity: 0.69 dl/g measured at 25°C in THF). The reshaping process was carried out at 140°C over 45 minutes. The radial stability was determined as above, the following changes resulted:

After days	Angling	Flattening
1	0.04 mm	
2	0.005 mm	
5	-	-
10	0.01 mm	
30	-	0.01 mm

Interferometer tests showed the freedom from haze of the lens, the freedom from tension and a surface roughness of less than 0.01 μm.

The defect scrap rate of the lenses manufactured according to this method with automated mass production lies below 15%, compared to 40 /11
to 60% in comparison to the usual sintering method from polymer powder.

Patent Claims /12

1. Method for manufacturing contact optical molded elements of transparent materials that can be thermoplastically processed by shaping under the effect of pressure and heating, characterized in that optically flawless blanks with the weight of the molded element to be produced are stamped or cut from a film of uniform thickness of the corresponding thermoplastic material and these are reshaped between two dies corresponding to the geometries of the molded elements to be manufactured in a molding tool at temperatures between 20 and 80°C over the glass transition temperature of the thermoplastic material, but still below its melting temperature.

2. Method according to Claim 1, characterized in that the film thickness is 0.1 - 1 mm.

3. Method according to Claim 2, characterized in that the film thickness is 0.15 - 0.5 mm.

4. Method according to Claims 1-3, characterized in that the weight of the blank is identical to that of the molded element to be produced, within ± 0.5 mg.

5. Method according to Claims 1-4, characterized in that the /13
pressure during reshaping is 1 - 100 kg/cm^2.

6. Method according to Claim 5, characterized in that the

pressure is at least 5 kg/cm^2.

7. Method according to Claims 1 - 6, characterized in that the duration of the reshaping process is 5 – 120 minutes.

8. Method according to Claim 7, characterized in that the duration is 20 – 60 minutes.

9. Method according to Claims 1 - 8, characterized in that the temperature during the reshaping process lies 20 – 60°C over the glass transition temperature of the thermoplastic material.

10. Method according to Claims 1 - 9, characterized in that semi-hard to hard organic polymers on the basis of cellulose esters of aliphatic C_2-C_4 carboxylic acids; homopolymers or copolymers of methacrylic and acrylic acid esters, styrene, acrylonitrile and vinyl chloride; polycarbonate; polyamide; and/or polymer blends on the basis of these polymers are used as thermoplastic materials.